DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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October 3, 2014

Reflexonic, LLC
% Julie Powell
Vice President, Quality Assurance
Emergo Group
816 Congress Ave., Suite 1400
Austin, TX 78701

Re: K142304
Trade/Device Name: Viberect Penile Vibratory Stimulation Device
Regulation Number: 21 CFR§ 884.5960
Regulation Name: Genital Vibrator for Therapeutic Use
Regulatory Class: II
Product Code: KXQ
Dated: August 15, 2014
Received: August 18, 2014

Dear Julie Powell,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR

Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner -S

for
Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K142304

Device Name
Viberect® Penile Vibratory Stimulation Device

Indications for Use *(Describe)*
Viberect® Penile Vibratory Stimulation Device is a hand held medical device indicated to provoke erections for men who experience erectile dysfunction.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

for

Viberect® Penile Vibratory Stimulation Device

1. Submission Sponsor

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USA
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Contact: Dr. Kambiz Tajkarimi, President

2. Submission Correspondent

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Contact: Julie Powell, VP, QA
Email: project.management@emergogroup.com

3. Date Prepared

August 15, 2014

4. Device Identification

Trade/Proprietary Name:	Viberect® Penile Vibratory Stimulation Device (Viberect)
Common/Usual Name:	Vibrator
Classification Name:	Vibrator for Therapeutic Use
Classification Regulation:	884.5960
Product Code:	KXQ
Device Class:	Class II
Classification Panel:	Obstetrics /Gynecology

5. Legally Marketed Predicate Device(s)

Viberect® Penile Vibratory Stimulation Device
Manufactured by Reflexonic, LLC
510(k) K110566

6. Device Description

The Viberect® device is a hand held medical device intended for use by the person at home for the purpose of stimulating the nerves of the penis for the purpose of activating several nerve reflexes which are responsible for initiation of penile erection and rigidity. This device is unique in that it has two gentle vibrating motors that allow simultaneous vibratory stimulation of both the upper and lower surfaces of the penis. As each side of the male penis is supplied by different nerves, simultaneous stimulation of the upper and lower surfaces increases sexual response.

The device is held by one hand easily, like holding a hair straightener. The penis is placed between the vibrating 'soft pads'. As pressure is increased to the device, it is automatically activated. The device can be deactivated by releasing the hand pressure which immediately shuts off the vibrating 'soft pads'. The touch pad on the Viberect provides further control by the user whereby the user can increase and decrease the frequency of vibration according to comfort and response. Finally, there are individual modes for the vibratory movement of the upper housing only, lower housing only, and both. The device is powered by rechargeable batteries. Vibratory stimulation for approximately 3-10 minutes is recommended.

7. Indication for Use Statement

Viberect® Penile Vibratory Stimulation Device is a hand held medical device indicated to provoke erections for men who experience erectile dysfunction.
For Over-the-Counter (OTC) use.

8. Substantial Equivalence Discussion

The following table compares the Viberect OTC device to the predicate device with respect to intended use, technological characteristics and principles of operation, providing more detailed information regarding the basis for the determination of substantial equivalence.

Table 12A – Device Comparison Chart: Similarities and Differences

	Proposed Device	**Predicate Device**	
Manufacturer	**Reflexonic, LLC**	**Reflexonic, LLC**	**Significant Differences**
Trade Name	Viberect Penile Vibratory Stimulation Device	Viberect Penile Vibratory Stimulation Device	
510(k) Number	NA	K110566	N/A
Product Code	KXQ	KXQ	Same
Regulation Number	884.5960	884.5960	Same
Regulation Name	Vibrator for Therapeutic Use	Vibrator for Therapeutic Use	Same
Indications for Use	Viberect® Penile Vibratory Stimulation Device is a hand held medical device indicated to provoke erections for men who experience erectile dysfunction.	Viberect® Penile Vibratory Stimulation Device is a hand held medical device indicated to provoke erections for men who experience erectile dysfunction and to provoke ejaculation for spinal cord injured men.	Removed the indication for use in spinal cord injured men, as recommended by the FDA
Intended for Prescription or OTC	OTC	Prescription	For OTC use; Usability study performed (per discussion with

	Proposed Device	Predicate Device	
Manufacturer	**Reflexonic, LLC**	**Reflexonic, LLC**	**Significant Differences**
Trade Name	Viberect Penile Vibratory Stimulation Device	Viberect Penile Vibratory Stimulation Device	
Use			the FDA); refer to Section 18 and Exhibit 18-D and 18-E for Usability Protocol and Report
Class	II	II	Same
Provided Sterile or Non-Sterile	Non-Sterile	Non-Sterile	Same
Basic Design	Hand held vibratory device which upon activation stimulates the nerves of the penis. This device has two gentle vibrating motors that allow simultaneous vibratory stimulation of both surfaces (top and bottom) of the penis.	Hand held vibratory device which upon activation stimulates the nerves of the penis. This device has two gentle vibrating motors that allow simultaneous vibratory stimulation of both surfaces (top and bottom) of the penis.	Same
Length	Approximately 10 inches	Approximately 10 inches	Same
Width	Approximately 2 inches (at widest point)	Approximately 2 inches (at widest point)	Same
Reusable	Yes – provided with cleaning instructions	Yes – provided with cleaning instructions	Same
Power Source	Rechargeable Nickel Metal Hydride (NiMH) batteries. Rechargeable (Ni-Cd) 6/1.2V/0.35Ah. The battery will last a minimum of 20 minutes (at 100hz and 2.5mm).	Rechargeable Nickel Metal Hydride (NiMH) batteries. Rechargeable (Ni-Cd) 6/1.2V/0.35Ah. The battery will last a minimum of 20 minutes (at 100hz and 2.5mm).	Same
Patient Contacting Materials	Vibrating Soft Pads Polyurethane/ Polyurethane Foam (IROGRAN®)	Vibrating Soft Pads Polyurethane/ Polyurethane Foam (IROGRAN®)	Same
Frequency	70-110 Hz	70-110 Hz	Same
Amplitude Range (peak to valley)	2 – 3 mm	2 – 3 mm	Same
Adjustability of above parameters	Full range by touch pad control	Full range by touch pad control	Same
Type of motion	Pulsatile	Pulsatile	Same
Auto safety shut off	Yes	Yes	Same
Complies with ISO 10993-1	Yes	Yes	Same
Charger, main voltage	100-120 / 200-240 volts	100-120 / 200-240 volts	Same
Electrical Safety Testing Passed	Yes	Yes	Same

9. Non-Clinical Performance Data

The following testing has been performed and determined to be acceptable to support substantial equivalence:

- Biocompatibility testing in accordance with ISO 10993-1
- Electrical Safety testing in accordance with IEC 60601-1
- Electromagnetic Compatibility testing in accordance with IEC 60601-1-2
- Usability testing

- Shipping testing
- Drop testing
- Cleaning testing

As part of demonstrating safety and effectiveness of Viberect device and in showing substantial equivalence to the predicate device that are subject to this 510(k) submission, Reflexonic, LLC completed a number of tests. The Viberect device meets all the requirements for overall design, biocompatibility, and electrical safety, and has been confirmed that the output meets the design inputs and specifications. The Viberect device passed all testing stated above as shown by the acceptable results obtained.

The Viberect device complies with the applicable voluntary standards for biocompatibility, electrical safety and electromagnetic compatibility. The device passed all the testing in accordance with national and international standards.

10. Clinical Performance Data

There was no clinical testing required to support the medical device as the indications for use is equivalent to the predicate device. The predicate device, Viberect has been on the market for several years with a proven safety and efficacy for the use of the device. The non-clinical testing detailed in this submission supports the substantial equivalence of the device.

Usability testing was performed and determined to be acceptable to support OTC indications for use.

11. Statement of Substantial Equivalence

By definition, a device is substantially equivalent to a predicate device when the device has the same intended use and the same technological characteristics as the previously cleared predicate device. The Viberect device has reduced the indications for use from the predicate device and has the identical technological characteristics as the predicate device. The new device does not raise different questions regarding its safety and effectiveness as compared to the predicate device.